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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,407	12/26/2001	Larry Caldwell	CALD-007	3764

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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,407

Applicant(s)

CALDWELL ET AL.

Examiner

Isis Ghali

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged applicants' amendment filed 11/09/2004.

Claims 1-23 are pending and included in the prosecution.

Claim Rejections - 35 USC § 102

1. Claims 1-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. (WO '978).

WO '978 discloses a method of relieving headaches by applying a topical formulation to the forehead, temple and occipital regions of the human head (examples 3-5, Cases 6 and 7). The topical formulation can be in the form of lotions, creams or transdermal pads (pg. 17, lines 3-6). The active agents include acetic acid derivatives such as diclofenac, indomethacin, ibuprofen, and ketoprofen (claims 7 and 8). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

2. Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Meyer et al. (WO '978).

As discussed above, WO '978 discloses formulations for the amelioration of migraine headaches topically. The reference also includes other applications in multiple

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cases studies. The patients in the case studies were given kits comprising a dosage form and instructions of how to use the dosage form (Case 5). Though the instructions were for a buccal administration, it can be assumed that instructions were given to each patient in the study regardless of the application sites and symptoms. Further it is a well-established practice to include instructions in commercially available topical analgesics purchased with or without a prescription. Such as Ben-Gay or Tiger Balm. With these things in mind it would have been obvious to follow the suggestions of WO '978 to include instructions with all of their dosage forms in order to safely instruct patients on proper use. It would have been obvious to a skilled artisan to follow these suggestions along with those trends established by commercially available products with an expected result of a kit comprising instructions and a topical analgesic.

Response to Arguments

3. Applicant's arguments filed 11/09/2004 have been fully considered but they are not persuasive. The main gist of applicants' argument against the anticipatory and obviousness rejections is that the claims as amended recite NSAID as the sole active agent in the topical formulation while the reference teaches NO which is an active agent as acknowledged by the reference.

In response to the above argument, the examiner position is the acknowledgement made by the reference regarding nitric oxide as an active agent is disclosed as part of the background of the invention wherein the reference referred to WO 93/17978 that teaches nitric oxide as an active agent in a topical dermatological

composition to treat skin, muscle and joint conditions. Therefore, nitric oxide was the active agent in WO 93/25213 and not in the recited reference in the current rejection. The instantly recited reference WO '978 teaches clearly nitric oxide as a medium to enhance the efficacy of analgesics, anti-inflammatory and/or antipyretic substances (abstract; page 5, lines 23-25; claim 1). Therefore, WO '978 anticipates claims 1-18 and makes obvious claims 19-23.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

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